



Victor Balancia
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1111 Pennsylvania Ave., NW
Washington, DC 20004

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,937,078 JAN 24 2007

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,937,078, which claims a method of using the animal drug product SURPASS® (diclofenac sodium), is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1,748 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1,748 days.

The period of extension has been calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of February 3, 2006, (71 Fed. Reg. 5859). Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,028) + 1,234 \\ &= 1,748 \text{ days (4.8 years)}\end{aligned}$$

Since the regulatory review period began March 6, 1998, after the patent issued (June 26, 1990), the entire regulatory review period has been considered in the above determination of the length of the extension period 35 U.S.C. § 156(c). No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

Neither the limitations of 35 U.S.C. § 156(g)(6) nor 35 U.S.C. § 156(c)(3) operate to reduce the period of extension determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,937,078
Granted:	June 26, 1990
Original Expiration Date ¹ :	August 26, 2008
Applicant:	Michael Mezei, et al.
Owner of Record:	Lipoderm Pharmaceutical Ltd.
Title:	Liposomal Local Anesthetic and Analgesic

¹Subject to the provisions of 35 U.S.C. § 41(b).

Product Trade Name: SURPASS® (diclofenac sodium)

Term Extended: 1,748 days


Expiration Date of Extension: June 9, 2013

Any correspondence with respect to this matter should be addressed as follows:

By mail: Mail Stop Hatch-Waxman PTE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450.

By FAX: (571) 273-7755

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7755.


Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 7
5600 Fishers Lane (Rockwall II Rm. 1101)
Rockville, MD 20857

Attention: Beverly Friedman

RE: SURPASS® (diclofenac sodium)
FDA Docket No.: 2004E-0389